

AUG 30 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESSK012507
10F2***The Trabecular Metal Technology Acetabular Augment System***

Submitter Name: Implex Corp.

Submitter Address: 80 Commerce Drive
Allendale, New Jersey 07401-1600

Contact Person: Robert A. Poggie, Ph.D.

Phone Number: (201) 818-1800

Fax Number: (201) 995-9722

Date Prepared: August 2, 2001

Device Trade Name: The Trabecular Metal Technology Acetabular Augment System

Device Common Name: Acetabular augmentation devices for total hip replacement acetabular components

Classification Number: 21 CFR § 888.3358

Substantial Equivalence: The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description: The TMT Acetabular Augment possesses a truncated hemispherical geometry with an inner diameter 3mm larger than the major diameter of the corresponding acetabular cup. The TMT Augment is available in OD sizes 40 to 70 mm in 2 mm increments, and each size is offered in various thicknesses, 5mm to 30mm in 5 mm increments. The TMT Acetabular Augment includes portals that allow the use of Continuum Bone Screws, 5mm and 6.5mm, and Zimmer Trilogy and HGP II 6.5 mm bone screws for adjunct fixation. In addition, the portals also provide a containment system for bone graft in cementless applications.

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510(k) Summary (Continued)

Indications for Use: The Trabecular Metal Technology Acetabular Augment System is intended to provide the orthopedic surgeon with a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.

Conclusion: The Trabecular Metal Technology Acetabular Augment System is substantially equivalent to the identified predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Robert A. Poggie, Ph.D.
Director of Applied Research
Implex Corporation
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K012507
Trade Name: The Trabecular Metal Technology Acetabular Augmentation System
Regulation Number: 888.3358
Regulatory Class: II
Product Codes: LPH
Dated: August 3, 2001
Received: August 6, 2001

Dear Dr. Poggie:

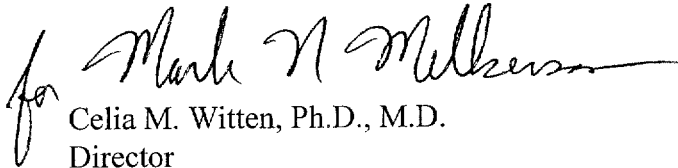
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Mark N. Millerson

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if
known):

K012507

Device Name:

The Trabecular Metal Technology Acetabular Augment
System

Indications For Use:

The Trabecular Metal Technology Acetabular Augment System is intended to provide the orthopedic surgeon with a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

for Mark H. Matthews
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Prescription
Use

(Per 21 CFR 801.109)

510(k) Number

OR...

Over-The-
Counter Use

K012507

(Optional Format 1-2-96)